**Appl. No.** : **10/807,643**
**Filed** : **March 23, 2004**

## REMARKS

This Amendment is in response to the Office Action mailed February 15, 2006 in the above captioned application. In the Office Action, Claims 23-42 were rejected over the prior art as discussed below. In this Amendment, Claim 42 has been amended. Claims 23-42 remain pending for further consideration.

Information Disclosure Statements

Applicant notes that an Information Disclosure Statement was filed on June 22, 2005 and that the Office Actions mailed to-date do not reflect the Examiner's consideration of the references listed therein. Applicant requests that the Examiner indicate that this Statement has been considered in the next paper.

Objections To The Specification and Drawing

The Examiner objects to the specification, stating that the term "os" should be given specific a meaning therein. Applicant notes that a similar objection was addressed in an *Amendment* filed April 11, 2005.

The Examiner's objection to the drawings relates to references in the specification to the structure labeled "16" in the figures as a "petal" and as an "anchor". Although the anchors are correctly described in the specification as "petal-like" in some embodiments, the specification has been amended to consistently use the term "anchor 16" throughout when referring to the embodiments shown in the figures. A typographical error has also be corrected.

In view of the amendments to the specification herein and in the April 11, 2005 *Amendment*, Applicant respectfully requests that the objections to the specification and drawings be withdrawn.

Rejections Under 35 U.S.C. § 112

Claim 42 was rejected because the limitation "the deployed second stent" was deemed to lack antecedent basis. This phrase has been amended to recite "the deployed second prosthesis" for which antecedent basis is provided in Claim 32. Applicant respectfully requests that the rejection of Claim 42 under 35 U.S.C. § 112 be withdrawn.

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Rejections Under 35 U.S.C. § 102

Claims 23-24, 27, and 32-41 were rejected in the Office Action as anticipated under 35 U.S.C. § 102(e) in view of Published Application No. 2005/0288769 listing Globerman as an inventor (Globerman). The Office Action states that Globerman teaches in connection with Figure 1d anchors/fingers "adapted to extend axially into and expandably circumscribe at least one-half of the main vessel (see Figure 1d) when the scaffold is implanted in the branch lumen...." Applicant disagrees with this assertion and traverses the rejection, as discussed further below.

Claims 23 and 32 and the claims that depend therefrom are not anticipated by Globerman. In order for a rejection under § 102(e) to be sustained, every element in the claim, in the same relationship as in the claim, must be disclosed in a single prior art reference. If even a single limitation in the claim is missing from the prior art reference, the rejection under §102 is improper and should be removed.

Here, Claim 23 contains at least one limitation that is not disclosed in Globerman. As a consequence, a rejection of Claim 23 and the claims that depend therefrom under §102(e) in view of Globerman would not be proper. For example, Globerman fails to disclose at least the following limitations of amended Claim 23:

> A prosthesis ... comprising: a radially expansible scaffold ... ; and at least two circumferential anchors extending axially from an end of the scaffold, said anchors adapted to extend axially into and expandably circumscribe at least one-half of the main vessel wall when the scaffold is implanted in the branch lumen with said one end adjacent the os....

To the contrary, Globerman describes a standard treatment of implanting a stent 110 near the ostium 104. See Paragraph [0080]. Globerman notes that one problem with such a treatment is assuring correct axial placement of the stent 110 in the ostium 104. Globerman suggests that correct axial placement can be achieved by limiting the advance of stent 110 by providing a flaring on the proximal end of the stent 110.

The flaring of the stent 110 to limit the advance thereof is illustrated in Figure 1D.

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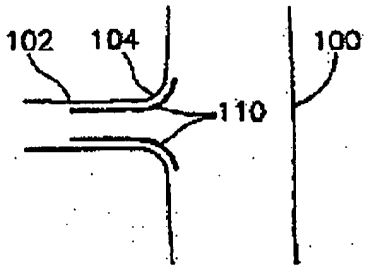



FIG.1D

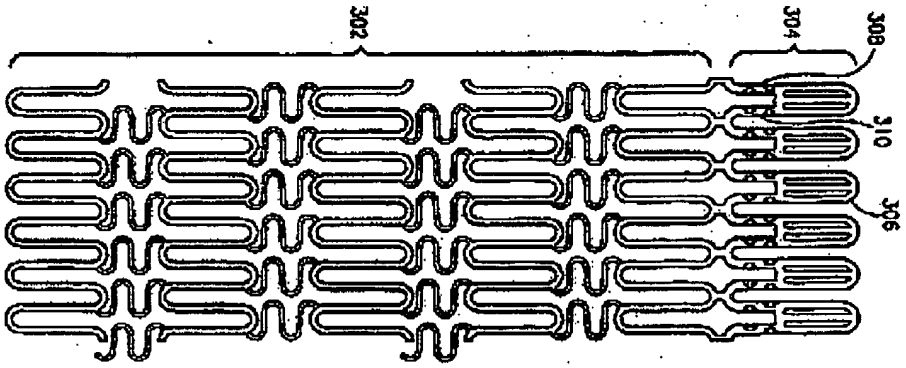
Applicants respectfully submit that, contrary to the Examiner's assertion, Globerman does not teach or suggest circumferential anchors that are adapted to extend axially into and expandably circumscribe at least one-half of the main vessel wall. To the contrary, Figure 1D shows that, at its farthest extent, the flaring of the stent 110 extends beyond the ostium into the main vessel by only a very small amount sufficient to assist in stent placement and thus circumscribes only a very small fraction of the main vessel wall.

Furthermore, when the short petals in Globerman (and in other short flange designs like US 6,096,074 to Yadav) are fully deployed as intended, they radiate in a star burst (or daisy) pattern (see Figure 9A and 9B in Globerman) to cap the ostium. Thus, some petals point upstream, some petals point downstream, and some petals point in a circumferential direction in the main vessel lumen.

In distinction, the significantly greater length of the anchors in Applicants' presently claimed design precludes such a deployed geometry. Upon full deployment of Applicants' prosthesis, at least a portion of each anchor extends in parallel with the longitudinal axis of the main vessel lumen. In addition, the anchors are long enough to remain spaced apart around the perimeter of the tubular zone defined by the long axis of the main vessel.

The Globerman petals are designed such that at least some of them are substantially perpendicular to the long axis of the main vessel with no component extending in parallel to the longitudinal axis of the main vessel lumen, and they are incapable of being spaced apart around the circumference of the main vessel lumen so that a second stent can be extended therethrough as with Applicants' claimed design.

Other embodiments of Globerman also do not teach or suggest anchors, e.g., structures of sufficient length to extend into the main vessel as recited in Claim 23. For example, Figure 3 of Globerman shows an ostial stent 300 that includes a cylindrical section 302 and a flaring section 304. The flaring section 304 includes a plurality of flare segments 306 that are attached to cylindrical section 302 by pairs of fingers 308 and 310.




The relative sizes of the flaring section 304 and the cylindrical section 302 taken in the axial direction is consistent with the teachings of Figure 1D and the written description of the stent 110. In particular, because the flaring section 304 is illustrated as being only a small fraction, i.e., about one-sixth, of the length of the stent 300, this embodiment also is not configured to expandably circumscribe at least one-half of the main vessel wall.

For at least these reasons, Globerman fails to disclose every limitation of Claim 23. Claims 24 and 27-30 depend from and further define the invention defined in Claim 23. Thus, these claims should be allowed at least for the same reasons that Claim 23 should be allowed over Globerman. Allowance of Claims 23, 24, and 27-30 over Globerman is respectfully requested.

Like Claim 23, Claims 32 contains at least one limitation that is not disclosed in Globerman. As a consequence, a rejection of Claim 32 and the claims that depend therefrom under §102(e) in view of Globerman would not be proper. For example, Globerman fails to disclose at least the following limitations of amended Claim 32:

> A method for deploying a prosthesis across an Os opening from a main lumen to a branch lumen, said method comprising: positioning a first prosthesis so that a scaffold lies within the branch lumen and at least two circumferential anchors extend into the main lumen; ... circumferentially deforming the anchors

> ... causing the anchors to ... open a passage through the anchors; and deploying a second prosthesis within the passage through the anchors.

To the contrary, as discussed above, Globerman teaches stents that are deployed in a branch vessel, e.g., the stent 110 and the stent 300. While these stents have flaring sections, these sections are too short to be deformed to open a passage through the flaring sections.

Furthermore, Globerman does not teach or suggest deploying a second prosthesis within a passage through anchors of a first stent. Globerman teaches in connection with Figure 9F that a stent that has a side opening should be used where a structure is to cover portions of main and branch vessels.

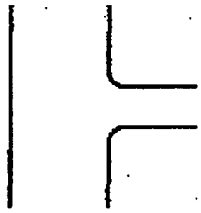


FIG.9F

The side opening is created by a ring of flare areas defined on a side wall of a stent. Because the structure of Figure 9F covers both the main vessel and the branch vessel portion, this arrangement does not teach or suggest deploying a second prosthesis within a passage through anchors, if anchors were provided.

For at least these reasons, Claim 32 is allowable over Globerman. Claims 33-41 depend from and further define the invention defined in Claim 32. Thus, these claims should be allowed at least for the same reasons that Claim 32 should be allowed over Globerman. Allowance of Claims 32-41 over Globerman is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 25-26, 31, and 41 were rejected in the Office Action as obvious in view of Globerman and U.S. Patent No. 6,589,274 to Steiger et al. (Steiger). Steiger is relied upon in the Office Action only for teaching a balloon with a radiopaque marker. Steiger has no teaching related to the shortcomings of Globerman in connection with Claims 23 and 32, discussed above.

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Accordingly, Applicant traverses these rejections because the combination, if proper, would not teach or suggest all of the limitations of these claims. Applicant reserves the right to contest the combinability of these references in a later paper.

For at least these reasons, Claims 25-26, 31, and 41 are allowable over the combination of Globerman and Steiger. Allowance of Claims 25-26, 31, and 41 over Globerman and Steiger is respectfully requested.

## CONCLUSION

In view of the foregoing, Applicants respectfully submit that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 28, 2006

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